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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,801	09/07/2004	Werner Mederski	MERCK-2916	5429
23599	7590	10/02/2006		
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER CHUNG, SUSANNAH LEE	
			ART UNIT 1626	PAPER NUMBER

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,801

Applicant(s)

MEDERSKI ET AL.

Examiner

Susannah Chung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are currently pending in the instant application and are subject to the following new lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-15 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Due to the numerous and widely divergent variables in the compound of formula (I), for example R, R1, R2, R3, etc., a precise listing of inventive groups cannot be made. The following groups are exemplary:

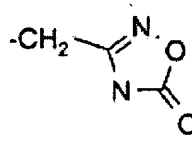
Group I: Claims 1-15 drawn to products and methods of using the compound of formula (I), wherein R is C(=NH)-NH₂, R1 is unbranched or branched alkyl having 1-20 carbons; R2 is phenyl with is monosubstituted by S(O)_pA; R3 is H; R4 is CHal₃, and the compound of formula (I) is used for the treatment of arteriosclerosis.

Group II: Claims 1-15 drawn to products and methods of using the compound of formula (I), wherein R is C(=NH)-NH₂, R₁ is Ar; Ar is phenyl; R₂ is phenyl with is monosubstituted by S(O)_pA; R₃ is H; R₄ is CHal₃, and the compound of formula (I) is used for the treatment of arteriosclerosis.

Group III: Claims 1-15 drawn to products and methods of using the compound of formula (I), wherein R is C(=NH)-NH₂, R₁ is Ar'; Ar' is (CH₂)_n-Ar; Ar is phenyl; R₂ is phenyl with is monosubstituted by S(O)_pA; R₃ is H; R₄ is CHal₃, and the compound of formula (I) is used for the treatment of arteriosclerosis.

Group IV: Claims 1-15 drawn to products and methods of using the compound of formula (I), wherein R is C(=NH)-NH₂, R₁ is unbranched or branched alkyl having 1-20 carbons; R₂ is phenyl with is monosubstituted by S(O)_pA; R₃ is H; R₄ is O(C=O)A; A is H, and the compound of formula (I) is used for the treatment of arteriosclerosis.

Group V: Claims 1-15 drawn to products and methods of using the compound of formula (I), wherein R is C(=NH)-NH₂, R₁ is unbranched or branched alkyl having 1-20 carbons; R₂ is



phenyl with is monosubstituted by S(O)_pA; R₃ is H; R₄ is , and the compound of formula (I) is used for the treatment of arteriosclerosis.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a method of use of said product) by identifying another specific

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embodiment, i.e. another value for R, R1, R2, R3, etc..., not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The technical feature of the instant claim(s) is the semicarbazide, which does not define a contribution over the prior art (as can be seen by Mederski et al., U.S. Pat. Num. 6,849,626, formula (I) of Claim 1, Column 31), which corresponds to applicants formula (I). The variables on the semicarbazide compound vary extensively and when taken as a whole result in vastly different compounds.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

A telephone call was made to Attorney Anthony J. Zelano on 09/11/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Telephone Inquiry

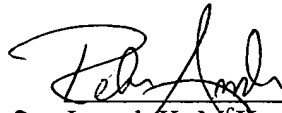
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
Patent Examiner, AU 1626


En Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 18 September 2006